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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/762,432 | 06/04/2001 | Seth P. Finklestein | 00786-400002 | 4601 |

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[REDACTED] EXAMINER

CHERNYSHEV, OLGA N

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

DATE MAILED: 04/10/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/762,432 | FINKLESTEIN, SETH P. | |
| | Examiner | Art Unit | |
| | Olga N. Chernyshev | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.

 4a) Of the above claim(s) 7-13 and 19-24 is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-6 and 14-18 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and "epidermal growth factor" as species of EGF-like polypeptides in Paper No. 7 is acknowledged.

Claims 7-13 and 19-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claims 1-6 and 14-18 are under examination in the instant office action.

Drawings

2. It is noted that the instant specification contains sequences in Figure 1 and sequences presented in separate listing. It is suggested that Fig.1 is deleted in order not to duplicate the information.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al. (WO 98/221127, May, 1998) in view of Peng et al. (Aplril, 1998, J. Cerebral Blood Flow and metabolism, 18, pp.349-360).

Reynolds et al. discloses methods for protecting neural tissue from the effects of insult, and neurological diseases or disorders by administering growth factors (EGF in particular) to the neural tissue of a mammal (see the abstract, also page 4, line 2, Example 2 on page 12 and claims 11-15). Neurodegenerative diseases, which intended to be treated by methods of Reynolds et al. include stroke and physical trauma to the central nervous system (page 1, lines 9 and 14). The document of Reynolds et al. teaches exogenous administration of EGF for such treatment (page 4, lines 9-13 and pages 8-9). Reynolds et al. do not expressly disclose a method of administration of EGF for reducing a neurological deficit in a patient with an injury to the CNS wherein administration of EGF commences more than 6, 12 or 24 hours after the injury (claims 14-16 of the instant application).

Peng et al. Disclose the information about EGF being a protective factor against forebrain ischemia-induced injuries (see the abstract). Peng et al. taught post-ischemic infusion of EGF (page 350, second column, last paragraph and page 351, first column, first paragraph) to reduce

neuronal damage caused by forebrain ischemia. According to Peng et al. experiments were done where EGF was infused into cerebral ventricles of ischemic animals after 3-minute forebrain ischemia and continued for seven days.

At the time the instant invention was made, it would have been obvious to a person of ordinary skill in the art to use the information provided by Peng et al. in the methods disclosed by Reynolds et al. One of ordinary skill in the art would have been motivated to do this because the disclosure of Reynolds et al. teaches methods for treating and protecting neural tissue from ischemia and trauma by administration of EGF before the insult or as a preventive measure and disclosure of Peng et al. teaches the beneficial effects of EGF on ischemia-induced neuronal damage even during post-ischemic administration.

Conclusion

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Art Unit: 1646

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
April 5, 2002

OC


JOHN ULM
PRIMARY EXAMINER
GROUP 1800